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## 8. 510(k) SUMMARY

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The Assigned 510(k) number is K032903.

**Submitter:**

ACON Laboratories, Inc.
4108 Sorrento Valley Boulevard
San Diego, California 92121

Tel.: 858-535-2030
Fax: 858-535-2038

**Date:**

September 12, 2003

**Contact Person:**

Edward Tung, Ph.D.

**Product Names:**

ACON® COC-150 One Step Cocaine Test Strip
ACON® COC-150 One Step Cocaine Test Device

**Common Name:**

Immunochromatographic test for the qualitative detection of Benzoylecgonine in urine.

**Classification Name:**

Cocaine test system.

**Device Classification:**

The Cocaine test systems have been classified as Class II devices with moderate complexity. The ACON COC-150 One Step Cocaine Test Strip and ACON COC-150 One Step Cocaine Test Device are similar to other FDA-cleared devices for the qualitative detection of Benzoylecgonine, a major cocaine metabolite, in urine specimens. These tests are used to provide only a preliminary analytical result. All positive test results obtained with these devices must be confirmed by another test method, preferably GC/MS analysis.

**Intended Use:**

The ACON® COC-150 One Step Cocaine Test Strip and ACON COC-150 One Step Cocaine Test Device are rapid chromatographic immunoassays for the qualitative detection of Benzoylecgonine in urine at a cutoff concentration of 150 ng/mL. They are intended for healthcare professionals including professionals at point-of-care sites.

**Description:**

The ACON COC-150 One Step Cocaine Test Strip and ACON COC-150 One Step Cocaine Test Device are competitive binding, lateral flow immunochromatographic assays for the qualitative screening of Benzoylecgonine in a urine sample. The test is based on the principle of antigen-antibody immunochemistry. It utilizes the antibody to selectively detect elevated levels of cocaine and its metabolite (Benzoylecgonine) in urine at a cutoff concentration of 150 ng/mL. These tests can be performed without the use of an instrument.

A drug-positive urine specimen will not generate a colored-line in the designated test region, while a negative urine specimen or a urine specimen containing Benzoylecgonine at the concentration below the cutoff level will generate a colored-line in the test region. To serve as a procedural control, a colored-line should always appear at the control region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

**Comparison to a Predicate Device:**

A comparison of the features of the ACON COC-150 One Step Cocaine Test Strip and ACON COC-150 One Step Cocaine Test Device versus a FDA-cleared cocaine test with 150 ng/mL benzoylecgonine cutoff is shown below:

- Both tests are assays intended for the qualitative detection of Benzoylecgonine in urine samples.
- Both tests are intended as a screening method that provides a preliminary analytical test result.
- Both tests are immunochromatographic, lateral flow assays for the rapid detection of Benzoylecgonine with a visual, qualitative end result.
- Both tests utilize the same basic immunoassay principles that rely on antigen/ antibody interactions to indicate a positive or negative result.
- Both tests have a cut-off Benzoylecgonine concentration of 150 ng/mL.

**Safety and Effectiveness Data:**

**Accuracy**

A clinical evaluation was conducted using 300 clinical urine specimens including approximately 10% of the specimens containing Benzoylecgonine concentration fell between –25% cutoff to +25% cutoff range. This evaluation compared the test results between ACON® COC-150 One Step Cocaine Test Strip and ACON® COC-150 One Step Cocaine Test Device with a FDA-cleared cocaine test; as well as compared against data obtained from the customary Gas Chromatography/Mass Spectrometry analysis. These comparisons of data yielded the following results:

**ACON COC-150 One Step Cocaine Test Strip** versus **FDA-cleared Cocaine Test**:

Positive Agreement: 141 / 141 = 100% (97.4% - 100%*)
Negative Agreement: 159 / 159 = 100% (97.7% - 100%*)
Overall Agreement: 300/300 = 100% (98.8% - 100%*)

* Since the proportion (%) cannot go above 100%, this is really a 97.5% Confidence interval.

**ACON COC-150 One Step Cocaine Test Device** versus **FDA-cleared Cocaine Test:**

Positive Agreement: 141 / 141 = 100% (97.4% - 100%*)
Negative Agreement: 159 / 159 = 100% (97.7% - 100%*)
Overall Agreement: 300/300 = 100% (98.8% - 100%*)

* Since the proportion (%) cannot go above 100%, this is really a 97.5% Confidence interval.

**ACON COC-150 One Step Cocaine Test Strip versus data obtained with GC/MS at the cutoff concentration of 150 ng/mL:**

| **Benzoylecgonine Conc. vs. Cutoff** | | **Negative** | **-25% Cutoff to Cutoff** | **Cutoff to +25% Cutoff** | **> +25% Cutoff** | **% Agreement with GC/MS** |
|---|---|---|---|---|---|---|
| **ACON COC-150 Test Strip** | **Positive** | 0 | 0 | 8 | 133 | 98.6% (95.0% - 99.8%)** |
| | **Negative** | 150 | 7 | 0 | 2 | 98.7% (95.5% -99.6%)** |

* Denotes 95% Confidence Interval.

**ACON COC-150 One Step Cocaine Test Strip versus data obtained with GC/MS at the cutoff concentration of 150 ng/mL**

| Benzoylecgonine Conc. vs. Cutoff | | Negative | -25% Cutoff to Cutoff | Cutoff to +25% Cutoff | > +25% Cutoff | % Agreement with GC/MS |
|---|---|---|---|---|---|---|
| ACON COC-150 Test Device | Positive | 0 | 0 | 8 | 133 | 98.6% (95.0% - 99.8%)** |
| | Negative | 150 | 7 | 0 | 2 | 98.7% (95.5% -99.6%)** |

* Denotes 95% Confidence Interval

**Performance Characteristics and Other information:**

The performance characteristics of ACON COC-150 One Step Cocaine Test Strip, ACON COC-150 One Step Cocaine Test Device were verified by analytical sensitivity study, specificity and cross reactivity study, interference studies, precision study, read time flex study, temperature flex study, specimen storage and stability study. Study results indicate that these test devices are robust and can perform satisfactorily when used according to the "Indication for Use" statement specified in their package inserts.

**Conclusion:**

These clinical studies demonstrated substantial equivalency on performance between the ACON COC-150 One Step Cocaine Test Strip, ACON COC-150 One Step Cocaine Test Device and a FDA-cleared cocaine test with the same cocaine cutoff concentration. It is also demonstrated that these tests are safe and effective in qualitatively detecting Benzoylecgonine at a concentration of 150 ng/mL. The POL study demonstrated that these tests are suitable for healthcare professionals including professionals at point-of-care sites.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 17 2004

Edward Tung, Ph.D.
Regulatory Affairs
ACON Laboratories, Inc.
4108 Sorrento Valley Blvd.
San Diego, CA 92121

Re: k032903
Trade/Device Name: ACON® COC-150 One Step Cocaine Test Strip
ACON® COC-150 One Step Cocaine Test Device
Regulation Number: 21 CFR 862.3250
Regulation Name: Cocaine and cocaine metabolite test system
Regulatory Class: Class II
Product Code: DIO
Dated: November 25, 2003
Received: January 6, 2004

Dear Dr. Tung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

## 11. INDICATIONS FOR USE

510(k) Number: K032903

Device Name: ACON® COC-150 One Step Cocaine Test Strip

ACON® COC-150 One Step Cocaine Test Device

Indications for Use:

The ACON COC-150 One Step Cocaine Test Strip and ACON COC-150 One Step Cocaine Test Device are rapid chromatographic immunoassays for the qualitative detection of Benzoylecgonine levels in urine at a designated cutoff concentration of 150 ng/mL. They are intended for healthcare professionals including professionals at point-of-care sites.

(Please do not write below this point)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ Or Over-The-Counter Use _____

(Per 21 CFR 801.109)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety



510(k) K032903